BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Medical Necessity Policy

Lung Cancer Agents – Unified Formulary

Policy Number: 9.712
Version Number: 2.1
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth- MCO ☒ MassHealth- ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Alecensa® (alectinib)	
Alunbrig® (brigatinib)	
Gilotrif® (afatinib)	
Iressa® (gefitinib)	
Lorbrena® (lorlatinib)	

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Tabrecta® (capmatinib)	
Tagrisso® (osimertinib)	
Tarceva® (erlotinib) *	
Tepmetko® (tepotinib)	
Vizimpro® (dacomitinib)	
Xalkori® (crizotinib)	
Zykadia® (ceritinib)	

*A-rated generic available. Both brand and A-rated generic require PA.

Approval Criteria:

Alecensa® (alectinib) **Zykadia®** (ceritinib)	1. Documented diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC); **AND** 2. Prescriber is an oncologist; **AND** 3. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive
Alunbrig® (brigatinib)	1. Documented diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC); **AND** 2. Prescriber is an oncologist; **AND** 3. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive
Gilotrif® (afatinib)	1. Documented diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC); **AND** 2. Prescriber is an oncologist; **AND** 3. **ONE** of the following: a. Documentation provided indicating member has epidermal growth factor receptor (EGFR) mutations; **OR** b. Documented inadequate response or adverse reaction to at least one platinum-based chemotherapy regimen OR contraindication to the use of platinum-based chemotherapy *(Note: History of claims is not sufficient)*
Iressa® (gefitinib) **Vizimpro®** (dacomitinib)	1. Documented diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC); **AND** 2. Prescriber is an oncologist; **AND** 3. Documentation provided indicating member has epidermal growth factor receptor (EGFR) mutations
Lorbrena® (lorlatinib)	1. Documented diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC); **AND** 2. Prescriber is an oncologist; **AND** 3. Documentation cancer is ALK-positive; **AND** 4. Documented inadequate response, adverse reaction or contraindication to Alecensa® (alectinib)

Tabrecta® (capmatinib)	1. Documented diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC); **AND** 2. Prescriber is an oncologist; **AND** 3. Documentation cancer has mutation that leads to MET exon 14 skipping
Tagrisso® (osimertinib)	1. Documented diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC); **AND** a. Prescriber is an oncologist; **AND** b. **ONE** of the following: i. Documentation cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **OR** ii. **BOTH** of the following: 1. Documentation cancer displays the EGFR mutation and the T790M resistance mutation; **AND** 2. Documentation member has had an inadequate response or adverse reaction to **ONE** of the following or contraindication to **ALL** of the following *(Note: History of claims is not sufficient)*: a. erlotinib b. Gilotrif® (afatinib) c. Iressa® (gefitinib) d. Vizimpro® (dacomitinib) **OR** 2. Documented diagnosis of Stage IIB to IIIA non-small cell lung cancer (NSCLC); **AND** a. Tagrisso will be used for adjuvant treatment; **AND** b. Prescriber is an oncologist; **AND** c. Documentation cancer displays the EGFR exon 19 deletions or exon 21 L858R mutation; **AND** d. Documentation member has completely resected disease; **AND** e. Documented inadequate response or adverse reaction to at least one platinum-based chemotherapy regimen OR contraindication to the use of platinum-based chemotherapy (*Note: Claims history is NOT sufficient*)
Tarceva® (erlotinib) *	*For advanced or metastatic non-small cell lung cancer* Prescriber provides documentation of **ALL** of the following: 1. Documented diagnosis of advanced or metastatic non-small cell lung cancer; **AND** a. Prescriber is an oncologist; **AND** b. Documentation member has EGFR mutations; **AND**

	c. **If request is for BRAND NAME Tarceva®**: Medical records documenting an inadequate response or adverse reaction to generic erlotinib are provided **OR** 2. Documented diagnosis of advanced or metastatic pancreatic cancer; **AND** a. Prescriber is an oncologist; **AND** b. Member will be using erlotinib in combination with gemcitabine; **AND** c. **If request is for BRAND NAME Tarceva®:** Medical records documenting an inadequate response or adverse reaction to generic erlotinib are provided
Tepmetko® (tepotinib)	1. Documented diagnosis of advanced or metastatic non-small cell lung cancer; **AND** 2. Prescriber is an oncologist; **AND** 3. Documentation cancer harbors MET exon 14 skipping alterations ** *Notes:* • ***Documentation of "MET-positive amplification" does not equate to MET exon 14 skipping alterations.*
Xalkori® (crizotinib)	1. Documented diagnosis of metastatic non-small cell lung cancer (NSCLC); **AND** a. Prescriber in an oncologist; **AND** b. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive or ROS1 positive **OR** 2. Documented diagnosis of systemic anaplastic large cell lymphoma (ALCL); **AND** a. Prescriber is an oncologist; **AND** b. Member is at least 1 year of age and less than 22 years of age; **AND** c. Documentation cancer is anaplastic lymphoma kinase (ALK)-positive; **AND** d. **ONE** of the following: i. Documentation cancer is relapsed or refractory to **ONE** prior regimen or agent† *(Note: History of claims is NOT sufficient);* **OR** ii. Clinical rationale as to why the other available treatment regimens cannot be used *Notes:* • †First-line options include: *Brentuximab vedotin + CHP (cyclophosphamide, doxorubicin, prednisone) (category 1), CHOP*

	(cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone), Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
Duration/Quantity of Authorization:	Prior authorization may be issued for **3 months.**
Recertification Criteria:	Resubmission by prescriber will infer a positive response to therapy and request can be recertified for **6 months**.

Appendix:

Additional Information

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a "Medically Accepted Indication" according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus. Requests for other diagnoses must be submitted with appropriate clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s).

References

1. Alecensa (alectinib) [prescribing information]. San Francisco, CA: Genentech, Inc.; November 2017.
2. Alunbrig (brigatinib) [prescribing information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; April 2017.
3. Gilotrif (afatinib) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. 2018 January.
4. Iressa (gefitinib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; 2015 July
5. Lorbrena (lorlatinib) [prescribing information]. New York, NY: Pfizer Labs; March 2021.
6. Tabrecta (capmatinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2020.
7. Tagrisso (osimertinib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2020.
8. Tarceva (erlotinib) [prescribing information]. Melville, NY: OSI Pharmaceuticals, Inc.; April 2010.
9. Tepmetko (tepotinib) [prescribing information]. Rockland, MA: EMD Serono, Inc.; February 2021.
10. Vizimpro (dacomitinib) [prescribing information]. New York, NY: Pfizer Labs; September 2018.
11. Xalkori (crizotinib) [prescribing information]. New York, NY: Pfizer Labs; January 2021.

12. Zykadia (ceritinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017 June.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	New policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
3/3/2021	Updated policy to reflect changes dated 2/6/21 from MH. Updated for new indication and criteria for Tagrisso, verbiage added for A-rated generic availability for Tarceva.	3/3/2021	P&T Committee
5/13/2021	No recommended changes or updates.	9/1/2021	P&T Committee
7/23/2021	Updated policy to reflect changes dated 6/24/21 from MH: Guideline updated to reflect new PA criteria for both Lorbrena (lorlatinib) and Xalkori (crizotinib) based on expanded indications.	9/1/2021	P&T Committee
10/1/2021	MH UPPL Update: Guideline updated to add one new agent, Tepmetko® (tepotinib), to UPPL. Guideline updated to reflect changes to Tagrisso (osimertinib) criteria based on NCCN guidelines for NSCLC (V5.2021).	1/1/2022	P&T Committee

Next Review Date

5/2022

Reference to Applicable Laws and Regulations, If Any

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provisions of the "Sullivan Law": (M.G.L. c.175, s.47K).

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.